

PTO-1449 REPRODUCED

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION
September 12, 2001
(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards and Jeffrey S. Hrkach

FILING DATE
March 30, 2001

GROUP
1615

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
Alf	AA	6,045,828	Apr-4-00	Bystrom et al.	424	489	
	AB	4,895,719	Jan-23-90	Radhakrishnan et al.	424	45	
	AC	5,993,805	Nov-30-99	Sutton et al.	424	94.1	
	AD	5,855,913	Jan-5-99	Hanes et al.	424	489	
	AE	5,985,309	Nov-16-99	Edwards et al.	424	426	
	AF	5,874,064	Feb-23-99	Edwards et al.	424	46	
	AG	6,077,543	20-Jun-00	Gordon et al.	424	489	
	AH	6,001,336	14-Dec-99	Gordon	424	46	
	AI	5,985,248	16-Nov-99	Gordon et al.	424	46	
	AJ	5,976,574	2-Nov-99	Gordon	424	489	
↓	AK	6,136,295	24-Oct-00	Edwards, et al.	424	45	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
Alf	AL	WO 97/41833	13 Nov 97	PCT			
	AM	WO 96/15814	30 May 96	PCT			
	AN	WO 97/26863	31 Jul 97	PCT			
	AO	WO 97/44012	27 Nov 97	PCT			
	AP	WO 91/16882	14 Nov 91	PCT			
↓	AQ	WO 98/31346	23 Jul 98	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Maa, Y., et al., "Spray-Drying of Air-Liquid Interface Sensitive Recombinant Human Growth-Hormone," <i>Journal of Pharmaceutical Sciences</i> Vol. 87(2):152-159 (1998).
AS	Mumenthaler, M., et al., "Feasibility Study on Spray-Drying Protein Pharmaceuticals--Recombinant Human Growth Hormone and Tissue-Type Plasminogen Activator," <i>Pharmaceutical Research</i> , Vol. 11(1):12-20 (1994).
AT	Broadhead, J., et al., "The Effect of Process and Formulation Variables on the Properties of Spray-dried β -Galactosidase," <i>J. Pharm. Pharmacol.</i> 46:458-467 (1994).

DATE CONSIDERED

1/23/02

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
<i>AAU</i>	AA2	RE37,053 E	13-Feb-01	Hanes, et al.	424	489	
	AN2	6,254,854 B1	3-Jul-01	Edwards, et al.	424	46	
	AC2	5,997,848	12-Jul-99	Patton, et al.	424	46	
	AD2	4,995,385	02-Feb-91	Valentini, et al.	128	203.21	
	AE2	4,069,819	24-Jan-78	Valentini, et al.	128	206	
	AF2	6,098,615	08-Aug-00	Lloyd, et al.	128	200.14	
	AG2	6,080,762	27-Jun-00	Allen, et al.	514	337	
	AM2	5,070,186	3-Dec-91	Joergensen	530	304	
	AI2	5,994,314	30-Nov-99	Eljamal, et al.	514	44	
	AJ2	5,474,978	12-Dec-95	Bakaysa, et al.	514	4	
✓	AK2	5,504,188	02-Apr-96	Baker, et al.	530	304	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO
	AL2	0-655-237-A1	31 May 95	EPO			
	AM2	0-317-120-A1	24 May 89	EPO			
	AN2	2,244,767	18 JAN 97	CAN			
	AO2	WO 00/10541	2-Mar-00	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AV	Patton, J., and Platz, R., "D) Routes of Delivery: Case Studies (2) Pulmonary Delivery of Peptides and Proteins for Systemic Action," Advanced Drug Delivery Reviews, 8:179-196 (1992).					
	AV	Niven, R., "Delivery of Biotherapeutics by Inhalation Aerosol," Critical Reviews in Therapeutic Drug Carrier Systems, 12(2&3):151-231 (1995).					
	AW	Ito et al., "Protein Location in Liposomes, A Drug Carrier: A Prediction by Differential Scanning-Calorimetry," Journal of Pharmaceutical Sciences, 84(7):805-814 (1995)					
EXAMINER <i>Smith, A.</i>			DATE CONSIDERED 7/23/02				

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<i>Steph</i>	AAB	5,534,488	09-Jul-96	Hoffmann	514	3	
	AB3	5,972,331	26-Oct-99	Reichert et al.	424	85.1	
	AC3	5,547,929	20-Aug-96	Anderson, Jr., et al.	514	3	
	AD3	5,461,031	24-Oct-95	DeFelippis	514	4	
	AB3	4,459,226	10-Jul-84	Grimes, et al.	260	112.7	
	AF3	5,941,240	24-Aug-99	Gonda, et al.	128	200.14	
	AG3	5,970,973	26-Oct-99	Gonda, et al.	128	200.14	
FOREIGN PATENT DOCUMENTS							
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AX	Vanbever et al., "Formulation and Physical Characterization of Large Porous Particles for Inhalation," Pharmaceutical Research, 16(11):1735-1742 (1999)					
	AY	Edwards, "The Macrotransport of Aerosol Particles in The Lung: Aerosol Deposition Phenomena," J. Aerosol Sci., 26(2):293-317 (1995)					
	AZ	Edwards et al., "Large Porous Particles for Pulmonary Drug Delivery," Science, 276:1868-1871 (1997)					
	AR2	French et al., "The Influence of Formulation on Emission, Deaggregation and Deposition of Dry Powders for Inhalation," J. Aerosol Sci, 27(5):769-783 (1996)					
	AS2	Hanes et al., "Porous Dry-Powder PLGA Microspheres Coated With Lung Surfactant For Systemic-Insulin Delivery VIA The Lung," Proceed Int'l. Symp. Control Rel. Bioact. Mater, pp.57-58 (1997)					
	AT2	Gupta et al., "Physical Characterization of Large Porous Particles for Inhalation," Pharmaceutical Research, (2000)					
EXAMINER <i>Steph</i>			DATE CONSIDERED 1/23/02				

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AU2		Vanbever et al., "Letter to the Editor", Pharmaceutical Research, (2000)					
AV2		Mintzcs, "The Spray Drying of Large, Porous Particles for Aerosol Drug Delivery to The Lung," The Pennsylvania State University, University Scholars Program, pp. 1-44, Thesis for baccalaureate degree (1998)					
AH2		Wang et al., "Inhalation of Estradiol for Sustained Systemic Delivery," J. of Aerosol Medicine, 12(1):27-36 (1999)					
AX2		Damgé, C., et al., "New Approach for Oral Administration of Insulin With Polyalkylcyanoacrylate Nanocapsules as Drug Carrier", Diabetes, 37:246-251 (1988)					
NY2		Ben-Jebria et al., "Large Porous Particles for Sustained Protection from Carbachol-Induced Bronchoconstriction in Guinea Pigs", Pharmaceutical Research, 16(4):555-561 (1999)					
AZ2		Andya et al., "The Effect of Formulation Excipients on Protein Stability and Aerosol Performance of Spray-Dried Powders of a Recombinant Humanized Anti-IgE Monoclonal Antibody," Pharmaceutical Research, 16(3):350-358 (1999)					
AR3		Broadhead, J., et al., "The Spray Drying of Pharmaceuticals," Drug Development and Industrial Pharmacy, 18(11&12):1169-1206 (1992)					
AS3		Nice, "Aerosol Properties of Large, Porous Particles for Inhalation," The Pennsylvania State University, University Scholars Program, pp. 1-59, Thesis for baccalaureate degree, (1998)					
AT3		Niven et al., "Abstracts for the International Society for Aerosols in Medicine 12 th Biennial Congress," J. of Aerosol Med., 12(2) sec. 73 (1999)					
AU3		Johnston et al., "Abstracts for the International Society for Aerosols in Medicine 12 th Biennial Congress," J. of Aerosol Med., 12(2) sec. 84 (1999)					
AV3		Scheuch et al., "Abstracts for the International Society for Aerosols in Medicine 12 th Biennial Congress," J. of Aerosol Med., 12(2) sec. 138 (1999)					
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AV3		Li et al., "Aerodynamics and Aerosol Particle Deaggregation Phenomena In Model Oral-Pharyngeal Cavities," J. Aerosol Sci. 27(8):1269-1286 (1996)					
AX3		Kawaguchi, H., et al., "Phagocytosis of Latex Particles by Leukocytes. I. Dependence of Phagocytosis on the Size and Surface Potential of Particles," Biomaterials 7:61-66 (1986)					
AY3		Krenis, L.J. and B. Strauss, "Effect of Size and Concentration of Latex Particles on Respiration of Human Blood Leucocytes," Proc. Soc. Exp. Med., 107:748-750 (1961)					
AZ3		Heyder, J., et al., "Deposition of Particles in the Human Respiratory Tract in the Size Range=0-0.005-15 µm," J. Aerosol. Sci., 17(3):811-825 (1996)					
AR4		Visser, J., "An Invited Review: Van der Waals and Other Cohesive Forces Affecting Powder Fluidization", Powder Technology, 58:1-10 (1989)					
AS4		Gonda, I., "Aerosols for Delivery of Therapeutic and Diagnostic Agents to the Respiratory Tract," in Critical Reviews in Therapeutic Drug Carrier Systems, 6:273-313 (1990)					
AT4		Gonda, I., "Physico-chemical Principles in Acrosol Delivery," in Topics in Pharmaceutical Sciences 1991, Crommelin, D.J. and K.K. Midha, Eds., Medpharm Scientific Publishers, Stuttgart, pp. 95-117 (1992)					
AU4		Morén, F., "Aerosol Dosage Forms and Formulations," in Aerosols in Medicine- Principles, Diagnosis and Therapy, Morén, et al., Eds., Elsevier, Amsterdam, 1985.					
AV4		Heinemann, L., et al., "Time-action Profile of Inhaled Insulin," Diabetic Medicine, 14:63-72 (1997)					
AW4		Abstract from Derwent Info Ltd., Access No. 1995-195390 / 199526					
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